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EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
10/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/536,887	HAISMAN ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,33 and 36-38* is/are pending in the application.

4a) Of the above claim(s) *13,14,21-30 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 15-20, 31 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/04/2010;07/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31, 33 and 36-38 are pending.

Election/Restrictions

Applicant's election with traverse of

Group I (claims 1-20, 31 and 36-38);

hydrolysis by enzymatic means with an enzyme from the specie *Kluyveromyces;*

isomerization by enzymatic means with an enzyme sourced for the species *Bacillus*;

oxidation by enzymatic means with an enzyme sources from *Penicillium*

and also elect catalase with the enzyme sourced from the specie *Aspergillus niger*;

in the reply filed on 07/29/2010 is acknowledged. The traversal is on the ground(s) that there should be no restriction between Groups I and II because Dake and Suzaki fail to disclose that the composition comprises oligosaccharides. This is not found persuasive because Suzaki discloses that the composition comprises about 2% oligosaccharides in line 9 of the abstract. Since lactose is not an oligosaccharide, the oligosaccharides must be non-lactose.

Applicants also argue that Groups I and IV should be rejoined because claim 33 recites a composition produced by the process of claim 31 which depends from claim 1 including non-lactose oligosaccharides, which Devos fails to disclose.

Group IV (claim 30) lacks a common special technical feature because a mother liquor as claimed is disclosed by the prior art as follows:

Abril et al. (1989) disclose a method for producing a whey syrup comprising hydrolyzing lactose present in ultrafiltration permeate of whey with an immobilized beta-galactosidase to produce galactose and glucose and isomerizing the glucose to produce fructose with

immobilized glucose isomerase. The process produces a whey syrup having glucose, fructose, galactose, small amounts of unhydrolyzed lactose and other oligosaccharides.

Abril et al. do not teach that the composition is treated with glucose oxidase to produce a composition including glucuronic acid and non-lactose disaccharides and further precipitating the galactose from the composition to obtain galactose crystals and a mother liquor.

Ramondetti discloses a method similar to Abril et al. for producing a syrup comprising galactose, fructose and glucose (abstract). Ramondetti teaches that it is possible to modify the percentage composition of the mixture in favor of fructose at a loss of glucose taking into account the interests of the market (col. 5, left col. lines 10-20).

Tegge teaches that a composition containing glucose and fructose can be enriched in fructose by subjecting the glucose in the mixture to oxidation with glucose oxidase to convert the glucose to gluconic acid (English abstract; p. 412, right col. to p. 413, left col.)

Clyne et al. disclose that galactose is a valuable product having use in the pharmaceutical industry or as a precursor for chemical and pharmaceutical synthesis. Galactose can be fractionally crystallized from a lactose hydrolysate that has been treated with glucose oxidase and catalase to make gluconic acid and that the galactose can be crystallized by differential precipitation (p. 3, lines 1-6 and abstract). The crystallization of galactose from the composition would naturally produce a mother liquor with the remaining components since the galactose has been crystallized out of the syrup composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Abril et al. to enrich the concentration of fructose by treating the composition with glucose oxidase. The ordinary artisan would have been motivated

to do so because Ramondetti teaches that it is desirable to enrich mixtures containing lactose, glucose and fructose in fructose according to the desired use of the sweetener. The ordinary artisan would have had a reasonable expectation that one could accomplish the enrichment of fructose at the loss of glucose by treating the composition with glucose oxidase Tegge teaches this process.

The references are silent regarding the formation of non-lactose disaccharides (claim 1) but meets the claimed limitations (lactose is treated with the claimed enzymes; hence, it naturally follows that the composition will contain the same products) which indicates that the claimed characteristics should be present in the prior art invention as also as those instantly claimed. In this case, burden is shifted to the Applicant to distinguish the instant invention over the prior art.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to differentially crystallize the composition of the combined references of Abril et al., Ramondetti and Tegge to obtain galactose crystals and the resulting mother liquor. The ordinary artisan would have been motivated to do so because the composition contains galactose which is a valuable commodity. The ordinary artisan would have been further motivated to do so because the removal of galactose results in a composition further enriched in fructose which can be

desirable for the use of the composition as a sweetener. The ordinary artisan would have had a reasonable expectation that one could obtain galactose crystals and a mother liquor from the composition of the combined references since Clyne et al. teach obtaining crystals from a similar composition.

Hence, the claims composition of Group IV is disclosed by the prior art and there is no special technical feature that defines a contribution for this Group over the prior art.

Claims 13, 14, 21-30 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07/29/2010.

It is noted that Applicants were required to elect species for the enzymes but have elected genera for the first three types of enzymes. This election is non-responsive but the election is moot since the enzyme species for all of the types of enzymes is withdrawn.

Claims 1-12, 15-20, 31 and 36-38 are presented for examination.

Claim Suggestion

It is suggested that the method claims be written in the active voice. For example, in claim 1, it is suggested that "hydrolysis of lactose" be change to "hydrolyzing lactose".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The composition of claim 1 comprises unconverted lactose and glucose. The indicated rejected claims include ranges that have zero percent lactose (claims 2, 4 and 8-10) and zero percent glucose (claim 8). The dependent claims are inconsistent with the composition of claim 1 because the dependent claims include a value wherein either unconverted lactose or glucose is not present in the composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, 15, 17-20 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abril et al. (1989) in view of Ramondetti (EP 499,165; cited in the IDS filed 07/14/2005), Tegge (1979) and Vroemen et al. (US 5,897,995).

Abril et al. disclose a method for producing a whey syrup comprising hydrolyzing lactose present in an ultrafiltration permeate of whey (claim 11) with an immobilized beta-galactosidase from *Kluyveromyces lactis* (claims 1, in part, 12 and 15) to produce galactose and glucose and isomerizing the glucose to produce fructose with immobilized glucose isomerase from *Streptomyces olivaceus* claims 1, in part, 17 and 18). The process produces a whey syrup having glucose, fructose, galactose, small amounts of unhydrolyzed lactose and other oligosaccharides (claim 1, in part). The syrup has potential use as a sucrose substitute (claim 38; p. 511, entire page). The enzymes can be added sequentially or together in one batch (p. 512, third full paragraph; claim 5).

Abril et al. do not teach that the composition is treated with glucose oxidase and catalase (claim 19) from the sources named in claim 20 to produce a composition including glucuronic acid and non-lactose disaccharides (claim 1), the order of the conversion steps including splitting of product streams (claims 6-10), the ratios of the components in the composition (claims 2-4 and 8-10), or adding the composition to a food product (claim 38).

Ramondetti discloses a method similar to Abril et al. for producing a syrup comprising galactose, fructose and glucose wherein whey is treated with lactase to produce glucose, galactose and lactose and the glucose is isomerized to fructose (abstract). Ramondetti teaches that it is possible to modify the percentage composition of the mixture in favor of fructose at loss

of glucose taking into account the interests of the market (col. 5, left col. lines 10-20). The composition can be used as a sweetening substance in food col. 5, lines 39-45; claim 38).

Tegge teaches that a composition containing glucose and fructose can be enriched in fructose by subjecting the glucose in the mixture to oxidation with glucose oxidase to convert the glucose to gluconic acid (claims 19, in part, claim 1, in part; English abstract; p. 412, right col. to p. 413 left col.)

Vroemen et al. teach that the combination of glucose oxidase and catalase convert glucose into gluconic acid. The enzymes can be obtained from an *Aspergillus niger* strain (abstract) or *Penicillium* (claims 19 and 20). The use of catalase is advantageous since it destroys the peroxide generated by the glucose oxidase reaction (col. 1, line 53 to col. 2, line 12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Abril et al. to enrich the concentration of fructose by treating the composition with glucose oxidase and catalase from *Aspergillus niger* or *Penicillium* (claims 1, 19 and 20). The ordinary artisan would have been motivated to do so because Ramondetti teaches that it is desirable to enrich mixtures containing lactose, glucose and fructose in fructose according to the desired use of the sweetener. The ordinary artisan would have had a reasonable expectation that one could accomplish the enrichment of fructose at the loss of glucose by treating the composition with glucose oxidase Tegge teaches this process.

The ordinary artisan would have been motivated to employ glucose oxidase and catalase sourced from *Aspergillus niger* or *Penicillium* since the combination of enzymes from said sources is known to effect the desired reaction (conversion of o glucose to gluconic acid). The ordinary artisan would have been motivated to employ catalase since it eliminates the peroxide

generated by the oxidase reaction. Peroxide is an oxidant that can spoil food and the ordinary artisan would reasonably want to avoid adding peroxides to food to avoid this. The ordinary artisan would have had a reasonable expectation that the combination of glucose oxidase and catalase from *Aspergillus niger* or *Penicillium* would catalyze the desired reaction since Vroeman et al. teach this.

The references are silent regarding the formation of non-lactose disaccharides (claim 1) but meets the claimed limitations (lactose is treated with the claimed enzymes; hence, it follows that the composition will contain the same products) which indicates that the claimed characteristics should be present in the prior art invention as also as those instantly claimed. In this case, burden is shifted to the Applicant to distinguish the instant invention over the prior art.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a composition comprising glucose, fructose, lactose, gluconic acid and non-lactose di- and oligo-saccharides as a sweetener for food since Abril et al. and Ramondetti suggest this use (claim 38). The ordinary artisan would have had a reasonable expectation that one could employ the composition as a sweetener since the composition is sweet..

It would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out the steps of the hydrolysis, oxidation and isomerization according to the orders as in claims 6-10. The ordinary artisan would have been motivated to do so to obtain a composition with the desired sweetness for food supplementation. Furthermore, the MPEP 2144.04 IV C states that the order of steps of a process is prima facie obvious in the absence of unexpected results.

Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

While the references listed above do not specifically teach the limitations of the concentration ranges of the components of the compositions resulting from the claimed method as seen in claims 2-4 and 8-10, one of ordinary skill in the art would recognize that the amounts of the components in the products is a result effective variable dependant on the desired sweetness of the product. This is motivation for someone of ordinary skill in the art to practice or test the parameter values widely to find those that are functional or optimal which then would be inclusive or cover that values as instantly claimed. Absent any teaching of criticality by the Applicant concerning the sweetness of the product of the composition, it would be prima facie obvious that one of ordinary skill in the art would recognize these limitations are result effective variable which can be met as a matter of routine optimization (MPEP § 2144.05 II).

Claims 1-12, 15-20 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abril et al. (1989) in view of Ramondetti (EP 499,165; cited in the IDS filed 07/14/2005), Tegge (1979) and Vroemen et al. (US 5,897,995), as applied to claims 1-12, 15,17-20 and 38, in further view of Bertelsen et al. (US 2003/0022844)

The combined closures by Abril et al. Ramondetti, Tegge and Vroemen et al. are discussed supra.

The combined disclosures do not teach that the beta-galactosidase (lactase) is sourced from *Sulfolobus solfataricus*.

Bertelsen et al. disclose a process to make tagatose by hydrolyzing lactose with lactase (beta-galactosidase) from *Sulfolobus solfataricus* and isomerizing the product to make tagatose (section [0074], Table 1 and claim 18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ lactase from *Sulfolobus solfataricus* instead of the hydrolase from *Kluyveromyces lactis* to carry out the hydrolysis step in the method of the combined disclosures. The ordinary artisan would have been motivated to do so each composition is known to have the same function, hydrolyzing lactose. Hence, the substitution is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another for a predictable result. The ordinary artisan would have had a reasonable expectation that one could successfully employ lactase from *Sulfolobus solfataricus* to carry out the hydrolysis step of the combined references since Bertelsen et al. disclose this.

Claims 1-12, 15, 17-20, 31 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abril et al. (1989) in view of Ramondetti (EP 499,165; cited in the IDS filed 07/14/2005), Tegge (1979) and Vroemen et al. (US 5,897,995), as applied to claims 1-12, 15, 17-20 and 38, in further view of Clyne et al. (WO 99/53088; cited in the IDS filed 7/14/2010).

The combined disclosures by Abril et al. Ramondetti, Tegge and Vroemen et al. are discussed supra.

The combined disclosures do not teach that galactose is precipitated and recovered from the mother liquor.

Clyne et al. disclose that galactose is a valuable product having using in the pharmaceutical industry or as a precursor for chemical and pharmaceutical synthesis. Galactose can be fractionally crystallized from any lactose hydrolysate that has been treated with glucose oxidase and catalase to make gluconic acid by differential precipitation (claims 1 and 4, p. 3, lines 1-6 and abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to differentially crystallize the composition of the combined references to obtain galactose crystals and the resulting mother liquor. The ordinary artisan would have been motivated to do so because the composition contains galactose which is a valuable commodity. The ordinary artisan would have been further motivated to do so because the removal of galactose results in a composition further enriched in fructose which can be desirable for the use of the composition as a sweetener. The ordinary artisan would have had a reasonable expectation that one could obtain galactose crystals and a mother liquor from the composition of the combined references since Clyne et al. teach obtaining crystals from a similar composition.

Claims 1-12, 15, 17-20, 31 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abril et al. (1989) in view of Ramondetti (EP 499,165; cited in the IDS filed 07/14/2005), Tegge (1979), Vroemen et al. (US 5,897,995) and Clyne et al. (WO 99/53088; cited in the IDS filed 7/14/2010), as applied to claims 1-12, 15, 17-20, 31 and 38, in further view of O'Sullivan et al. (US 2004/0013769).

The combined disclosures by Abril et al. Ramondetti, Tegge, Vroemen et al. and Clyne et al. are discussed supra.

The combined disclosures do not teach that the mother liquor resulting from the galactose crystallization is used to sweeten a food product.

O'Sullivan et al. disclose that fructose syrups can be used to sweeten milk products (section [0033]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the mother liquor obtained from the galactose crystallization of the composition of the combined references as a sweetener for milk products. The ordinary artisan would have been motivated to do so because the mother liquor is a fructose syrup which can be used as a sweetener as disclosed by O'Sullivan et al. The ordinary artisan would have had a reasonable expectation that one could employ the mother liquor as a sweetener since it has a necessary component for sweetening, fructose.

Roberts et al. J. Dairy Science (1953) 36: 620-632 is made of record as it demonstrates the production of oligosaccharides from the hydrolysis of lactose by beta-galactosidase.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Irene Marx/
Primary Examiner
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